

# Transvaginal hydrolaparoscopy

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## SUMMARY AND GENERAL DISCUSSION

Subfertility, defined as the non-occurrence of pregnancy after 12 months of unprotected intercourse, affects approximately one in six couples that are trying to conceive. In the work-up for subfertility there are different diagnostic procedures to determine the cause of subfertility and to determine the subsequent treatment if needed.

This thesis focuses on two different methods of tubal patency testing in the work-up for subfertile women: THL and HSG. Both are established diagnostic procedures for tubal patency. They have different characteristics, such as invasiveness of the procedure, pain during the procedure, and different ways of visualization either via radiological images of the uterine cavity and tubes versus direct visualization of the tubes, fimbrial ends and ovaries with an endoscope.

We investigated the prognostic value of THL in a retrospective cohort of women that underwent THL as a first-line tubal patency test. We compared both diagnostic procedures in a randomised controlled trial. We investigated if a diagnostic strategy starting with THL was non-inferior to HSG in the workup for subfertility. Alongside this trial we investigated the cost-effectiveness of the two procedures. Furthermore we explored fertility-related quality of life in women undergoing these procedures and we assessed which characteristics of the diagnostic procedures for tubal patency testing are most important for women that are undergoing a fertility work-up.

## SUMMARY

In a multicenter retrospective cohort we studied 1,033 women that underwent THL as their first-line tubal patency test in their subfertility work-up. In **CHAPTER 2** we describe the findings of their THL-procedures and the subsequent pregnancy rates. The primary outcome measure was intrauterine pregnancy, either after natural conception, ovulation induction or after treatment with controlled ovarian stimulation and intrauterine insemination (non-IVF conceptions). Cumulative intrauterine pregnancy rates were calculated using Kaplan–Meier analysis and fecundity rate ratios (FRR) were established. THL showed bilateral patent tubes in 83%, one-sided tubal occlusion in 12.4% and bilateral tubal occlusion in 4.6% of women. Cumulative intrauterine pregnancy rates after 36 months were 52% for women with bilateral patent tubes, 44% for one-sided tubal occlusion (FRR 1.04; 95% confidence interval [CI], 0.78 to 1.39) and 7% for bilateral tubal occlusion (FRR 0.13; 95% CI, 0.04 to 0.43). Endometriosis was diagnosed in 6.4%, and adhesions in 9.1%, while 3.9% of women had both. Corresponding FRR were 0.73 (95% CI, 0.49 to 1.09), 0.68 (95% CI, 0.46 to 1.02) and 0.42 (95% CI, 0.20 to 0.84).

We conclude that both bilateral tubal occlusion and the combination of endometriosis and adhesions strongly reduce the chance of a non-IVF pregnancy, while women with either adhesions or endometriosis have a limited reduction of their fertility chances. One-sided tubal occlusion did not have impact on non-IVF conception.

In **CHAPTER 3** we describe the results of our multicenter randomised controlled trial comparing THL and HSG as a first-line tubal patency test in subfertile women. Subfertile women scheduled for tubal patency testing were eligible. Women with a positive Chlamydia PCR, prior tubal testing or tubal surgery, a retroverted uterus, masses or cysts in the pouch of Douglas, and allergies to iodine or methylene blue were excluded. The primary outcome was conception leading to live birth within 24 months after randomisation. We allocated 149 women to a strategy with THL and 151 to a strategy with HSG. We were able to achieve complete follow-up in 142 versus 148 women. After the fertility work-up women were treated according to the Dutch guidelines and based on the prognostic model of Hunault. From the intention-to-treat population, 83 women from the THL group (58.5%) conceived and delivered a live born child within 24 months after randomisation compared with 82 women (55.4%) in the HSG group (difference 3.0%, 95% CI -8.3 to 14.4). Time to conception leading to live birth was not statistically different between groups. Miscarriage and multiple pregnancies were not statistically different in the two groups. Ectopic pregnancy was only found in the HSG group (2 women) and not in the THL group. We conclude that in a preselected group of subfertile women with a low risk of tubal pathology, use of a strategy with THL was not inferior to a strategy with HSG for predicting conception leading to live birth.

In **CHAPTER 4** we evaluate the cost-effectiveness of a diagnostic strategy starting with THL with a strategy starting with HSG in the subfertility work-up. We performed an economic evaluation of our multicentre randomised controlled trial comparing THL and HSG in 300 subfertile women. The mean costs and outcomes for each treatment group were compared. We used a non-parametric bootstrap resampling of 1,000 re-samples to investigate the effect of uncertainty and we created a cost-effectiveness plane and cost-effectiveness acceptability curves. The mean costs per woman were lower in the THL group, compared to the HSG group (THL group €4991 versus €5262 in the HSG group, mean cost difference = -€271 (95% CI -€273 to -€269)). Although the costs of the diagnostic procedure itself were higher in the THL group, the total costs were higher in the HSG group, because more women underwent diagnostic and therapeutic laparoscopies and also had higher costs for fertility treatments. The findings of our trial suggest that a strategy starting with THL is more cost-effective compared to a strategy starting with HSG in the workup for subfertile women.

We asked the women participating in the THL-trial to score their fertility-related QoL on the validated FertiQoL questionnaire six weeks after the procedure. In **CHAPTER 5** we describe the findings of this study. The scores for the Core scale and subscales between THL and HSG were compared using Mann-Whitney-U test and multiple linear regression analysis. The questionnaire was completed by 84 women in the THL group and 96 women in the HSG group. We found scores on the different domains of the FertiQoL questionnaire comparable between the two groups. The multiple linear regression analysis showed only a statistical significant positive effect of older age on the score for the Emotional domain.

We investigated in women with an indication for tubal patency testing, what their preferences are for characteristics of the diagnostic procedures HSG and THL. In **CHAPTER 6** we present the results of our discrete choice experiment (DCE). We defined attributes based on literature review, structured patient interviews and expert focusgroup meetings. We designed a labeled DCE, in which women were asked to choose between choice sets with hypothetical scenarios of two tubal patency tests with different levels of the attributes. Data were analysed by using multinomial logistic regression. We found that for THL women preferred a lower chance of a false negative result, a lower failure rate and a shorter waiting time. If a THL is not conclusive or failure to reach the pouch of Douglas, women prefer to have a conventional laparoscopy over expectant management. Women choosing HSG preferred a lower chance of a false negative result, a shorter waiting time and a lower chance of complications.